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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,825	12/22/2000	Stephen Grimes	1102865-0036	4304

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EXAMINER

HUYNH, PHUONG N

ART UNIT PAPER NUMBER

1644

DATE MAILED: 10/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/747,825

Applicant(s)

GRIMES ET AL.

Examiner

"Neon" Phuong Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 3/12/02, 2/14/02, 7/30/02.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 & 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. Claims 35-52 are pending.
2. Applicant's election with traverse of Group I, Claims 35-52 drawn to an immunogenic composition comprising an aqueous immunogen and a pharmaceutically acceptable oily vehicle wherein the immunogen comprises a gastrin-17 (G17) conjugated to an immunogenic carrier optionally linked through a spacer peptide and a method for formulating said composition that read on Montanide ISA 703, filed 7/30/02, is acknowledged. The traversal is on the grounds that (1) the claimed invention of the claims 35-52 cannot be divided into Groups I, II and III since the surprising discovery of frozen storage stability is not related to the type of immunomimic peptide regardless whether the antigenic target is G17, G34 or GnRH, (2) all pharmaceutically acceptable oily vehicle such as ISA 25, ISA 720 have been found suitable for stable frozen storage emulsions of the injectable immunogenic composition regardless of the immunogenic conjugate involved. This is not found persuasive because of the reasons set forth in the restriction mailed 5/21/02. Further, a prior art search also requires a literature search. It is a burden to search more than one invention. Therefore, the requirement of Group I and Groups II-III is still deemed proper and is therefore made FINAL.
3. Claims 35-52, drawn to an immunogenic composition comprising an aqueous immunogen and a pharmaceutically acceptable oily vehicle wherein the immunogen comprises a gastrin-17 (G17) conjugated to an immunogenic carrier optionally linked through a spacer peptide and a method for formulating said composition that read on Montanide ISA 703, are being acted upon in this Office Action.
4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:  

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 35-37, 41-42 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat No 5,424,067 (June 1995, PTO 1449).

The '067 patent teaches an immunogenic composition such as a vaccine formulated in an emulsion comprising an oily vehicle such as squalene, squalane and spermaceti oil and the aqueous phase (buffer) containing any antigen such as Influenza virus in addition to lecithin and PEG monooleate as emulsifier (See abstract, column 3, lines 31-33, in particular). The reference composition is stable for at least 12 months and over a year in storage at 4°C (See abstract, column 4, line 24, claims 1, 2, 5 of the '067 patent, in particular). The reference composition is formulated as a mixture of water (buffer) in oil in water multiphase solutions (W/O/W) (See abstract, in particular). The term "comprising" is open-ended. It expands the claimed immunogenic composition to include additional compound in the composition. The reference composition is stable in cold storage and in freezing temperature because of the inherent property of the reference squalene and squalane. Claim 44 is included in this rejection because the claimed composition appears to be the same as the reference composition and the increased in immunogenicity upon storage is an inherent properties of the reference composition because the reference squalene and squalane are oil which have the characteristics of adjuvant such as increase antibody level in mice (See column 4, line 49-51, in particular). Thus, the reference teachings anticipate the claimed invention.

6. Claims 35-38, 41-42 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat No 5,109,026 (April 1992, PTO 1449).

The '026 patent teaches an immunogenic composition such as a vaccine formulated as an emulsion water-in-oil comprising an aqueous immunogen such as LHRH or estrogen 17 $\beta$ -6CMO conjugated to human serum albumin dissolved in saline and emulsified with a pharmaceutically acceptable oily vehicle such as squalene (See column 6, lines 13-16, column 6, lines 50-55, in particular). The reference immunogenic composition is formulated as water in oil (See claim 5 of the '026 patent, in particular). The reference composition is stable in cold storage or in freezing temperature because of the inherent oily property of the reference squalene and squalane. Claims 41-42 are included in this rejection because the claimed composition appears to be the same as the reference composition which is stable in cold storage that can last at least a year due to the inherent property of the reference oily vehicle squalene. The reference composition is stable in cold storage and in freezing temperature because of the inherent property of the reference

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squalene and squalane. The '026 patent teaches the reference squalene and squalane have immunoadjuvant property that enhance the immunogenicity of the reference composition such as potentiating the anti-hormone antibody responses in vaccinated animals (See entire document, claim 4 of '026 patent, column 3, lines 65-66, in particular). The term "comprising" is open-ended. It expands the claimed immunogenic composition to include additional compound in the composition. Thus, the reference teachings anticipate the claimed invention.

7. Claims 35-52 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat No. 5,468,494 A (Nov 1995, PTO 1449).


The '494 patent teaches an immunogenic composition comprising an emulsion such as oily vehicle Montanide ISA type 703 and an aqueous immunogen such as gastrin 17 conjugated to an immunogenic carrier such as diphtheria toxoid, tetanus toxoid and keyhole limpet hemocyanin in PBS and aluminum monostearate (See column 4, example 4, claims 1-5 of '494 patent, in particular). The '494 patent further teaches a method for formulating the reference immunogenic composition by mixing an aqueous immunogen such as gastrin 17, which is a hormone immunomimic peptide fragment, coupled to an immunogenic carrier such as DT in PBS with a pharmaceutically acceptable oily vehicle in an oil-in-water or water-in-oil formulation wherein the suitable oily vehicle is Montanide type ISA 703 (See column 4, lines 25-65, in particular). The reference method of formulating the reference immunogenic composition is stable in storage for a minimal of several weeks, which is more than one day or at least one month (see column 4, lines 37-40, in particular). The term "comprising" is open-ended. It expands the claimed immunogenic composition to include additional compound in the composition. The claimed composition appears to be the same as the reference composition. The reference composition is stable in cold storage that can last at least 8 days, a year, or in freezing temperature because of the inherent property of the reference mineral oil, Montanide type ISA 703. The increase in immunogenicity upon storage is also an inherent property of the reference mineral oily vehicle Montanide type ISA 703 in composition. Claims 50-52 are included in this rejection because the integrity of the reference composition is an inherent property of the reference mineral oil Montanide type ISA 703 in the reference composition. Thus, the reference teachings anticipate the claimed invention.

8. No claim is allowed.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.
10. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Phuong N. Huynh, Ph.D.  
Patent Examiner  
Technology Center 1600  
October 21, 2002

  
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